

## **REMARKS**

Claims 85 and 86 are pending in the application.

- Claim 85 is rejected under 35 USC 112, second paragraph (indefiniteness).
- Claims 85 and 86 are rejected under 35 USC 112, second paragraph (enablement).
- Claim 86 is rejected under 35 USC 102(b).
- Claim 85 is rejected under 35 USC 103(a)

### **Amendments to the Claims**

Claims 85 and 86 are amended to include, in part, the element of "...an antibody generated to the central region of beta-amyloid [SEQ ID NO.: 3]..." Support for the amendment can be found in paragraphs [0127] – [0129] and Table 8 of the pending specification. The amendments add no new matter to the specification.

### **Examiner Interview**

A telephonic interview was held between Examiner MacFarlane and Applicant's representative David Wilson on September 16, 2009. The Examiner is thanked for her helpfulness and courtesy during the interview. The pending 102 and 103 rejections were discussed as well as the pending 112, indefiniteness rejection.

### **Rejection under USC 35, 112, second paragraph (Indefiniteness)**

The Examiner has rejected Claim 85 as being indefinite in regard to the phrase "physiological levels of albumin."

Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

MPEP, 2173.02

and,

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine **whether the claim apprises one of ordinary skill in the art of its scope** and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent.

MPEP, 2173.02, **emphasis added**.

One of skill in the art understands that "physiological levels of albumin" constitute a physiological range. The Examiner has generously provided teachings demonstrating that one of ordinary skill in the art would be apprised of the scope of the claim containing the phrase "physiological levels of albumin" by presenting references by those of skill in the art demonstrating the range of physiological levels of serum albumin. See, pending Office Action, page 4. In view of the Examiner's largess, the Applicant respectfully requests the withdrawal of the rejection.

**Rejection under USC 35, 112, first paragraph (Enablement)**

The Examiner has rejected Claims 85 and 86 as containing subject matter that is not described in the specification in such a way as to enable one skilled in the art to which it pertains. The presently pending claims have been amended to recite, in part, the element of "...an antibody generated to the central region of beta-amyloid [SEQ ID NO.: 3]." To the best of the Applicant's knowledge, antibodies generated to the central region of beta-amyloid [SEQ ID NO.: 3] of beta-amyloid were not known in the art before the present invention. Support for this amendment can be found in the pending specification at, for example, paragraphs [0067], [0074]. These paragraphs and Table 2 also provide support for the ability of antibodies generated to SEQ ID NO.: 3 to bind full-length beta-amyloid.

The Applicant submits that the present invention is enabled as claimed. The art of antibody production is a mature art. In other words, one of skill in the art would understand how to make antibodies without undue experimentation. The inventiveness of the invention is not the production of antibodies, however, but rather in the unexpected and surprising result achieved by the Applicant to form immunological complexes between anti-beta-amyloid antibodies and beta-amyloid in levels of human albumin at about 60 mg/ml or at physiological levels. This is contrary to teachings in the art (see, discussion regarding Matsumoto, et al., below).

That the antibodies made by the methods of the present invention can function markedly differently from the antibodies of Matsumoto, et al., can be easily understood. Not all antibodies made to a target may be the same. For example, the target may contain numerous epitopes. Antibodies can vary markedly in, for example, specificity, affinity and avidity. Thus, it is not surprising that the antibodies made to the epitope of the present invention function differently than those of the prior art.

In regard to the antibodies of the present invention, the antibodies were generated by immunization with a specific epitope of beta-amyloid: SEQ ID NO.: 3. Without necessarily agreeing to the Examiner's reasoning, the claims have been amended to reflect this. In view of the amendment to the claims the Applicant submits that the pending claims are enabled and respectfully request the withdrawal of the pending rejection.

**Rejection under 35 USC, 102(b)**

The Examiner has rejected Claims 86 under 35 USC, 102(b) as being anticipated by Terryberry, *et al.* Applicant respectfully traverses the rejection in view of the pending amendments.

Without necessarily acquiescing to the Examiner's remarks Applicant has amended the Claim to recite "...in the presence of ~~up to~~ about 60 mg/ml of human serum albumin." Terryberry, *et al.*, does not teach this element of amended Claim 86 and, therefore, can not anticipate the Claim. Applicant has also amended the claim as discussed above. In view of these amendments, the Applicant respectfully requests the withdrawal of the pending rejection and allowance of the claim.

**Rejection under 35 USC, 103(a)**

The Examiner has rejected Claim 85 as unpatentable under 35 USC, 103(a) by Terryberry in view of Matsumoto, *et al.* The Applicant traverses this rejection in view of the pending amendments.

The Examiner states "Terryberry does not teach the detection of an antigen-antibody complex in the presence of physiological levels of human serum." The Applicant agrees. The Examiner further states "Matsumoto explicitly teaches human albumin as a protein that binds specific epitopes of beta-amyloid and APP and serves to mask antibody binding." The Examiner then asserts that one of skill in the art would be motivated to use the system of Matsumoto to test binding of anti-beta-amyloid bodies to beta-amyloid to detect binding in the presence of physiological levels of albumin. Applicant submits that this is a mischaracterization of the Matsumoto reference. Matsumoto teaches the masking of epitopes on beta-amyloid by albumin. "The unique feature of human albumin ... seems to be its masking activity for epitope(s) in  $\beta$ -amyloid..." Matsumoto, page 3301. And, "Western blot analysis with domain-specific AAP [beta-amyloid precursor protein] antibodies revealed that the masking activity [of albumin for  $\beta$ -amyloid] is complete for  $\beta$ -amyloid epitope(s)." Matsumoto, abstract.

Thus, and contrary to the Examiner's assertion, Matsumoto actually teaches that the ability of a beta-amyloid antibody to bind beta-amyloid in physiological levels of albumin is unexpected and surprising in the art. In other words, Matsumoto cannot teach the binding of an antibody to beta-amyloid in physiological levels of albumin if Matsumoto teaches that it can not be done. In sharp contrast to the art, the Applicant has had unexpected success where Matsumoto has failed and where Matsumoto has taught the art to expect failure. In other words, Matsumoto teaches against the present invention.

Applicant submits that if both Terryberry and Matsumoto fail to teach the binding of an anti-beta-amyloid antibody to beta-amyloid in the presence of physiological levels of human albumin then the combination of art cannot render the pending claim as obvious.

The Applicant further submits that the failure taught by the Matsumoto would not provide one of skill in the art the motivation to form immune complexes between anti-beta-amyloid antibodies and beta-amyloid in levels of human albumin at about 60 mg/ml or at physiological levels since Matsumoto teaches it cannot be done. Further, neither Terryberry nor Matsumoto, alone or in combination, teach or fairly suggest the element of an antibody generated to the central region of beta-amyloid [SEQ ID NO.: 3], as is presently claimed in the instant invention. Thus, Terryberry in view of Matsumoto cannot teach, fairly suggest or render predictable the presently claimed invention. In view of these arguments the Applicant respectfully requests the withdrawal of the pending rejection and allowance of the claim.

**Summary**

In light of the above amendment and attendant remarks, consideration of the subject patent application is respectfully requested. If an interview would be beneficial to the prosecution of this case, Applicants respectfully request that Examiner MacFarlane contact the representatives of record. Any deficiency or overpayment should be charged or credited to Deposit Account No. 50-4514.

Respectfully submitted,

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